

Attorney Docket No.: **SJ-0011**  
Inventors: **Danks et al.**  
Serial No.: **09/622,568**  
Filing Date: **August 31, 2000**  
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#### **REMARKS**

Claims 23, 25, and 27-29 are pending in the instant application. Claims 23, 25, and 27-29 have been rejected. Claim 23 has been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

#### **I. Rejection Under 35 U.S.C. §112**

Claims 23, 25, 27 and 28 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner suggests that the recitation of "rabbit carboxylesterase which expresses a polynucleotide encoding SEQ ID NO:21" in claim 23 is confusing as proteins do not express polynucleotides but are produced from the expression of polynucleotides.

To facilitate the prosecution of the instant application, Applicants have amended claim 23 to recite that the rabbit carboxylesterase is produced by expressing a polynucleotide encoding SEQ ID NO:21. Withdrawal of this rejection is therefore respectfully requested.

#### **II. Rejection Under 35 U.S.C. §103**

Claims 23, 25, 27 and 28 are rejected under 35 U.S.C. §103(a) as being as being unpatentable over Senter et al. (Reference AG of Applicant's PTO-1449) in view of Danks et al. (Reference AB of Applicant's PTO-1449) and Satoh et al. (Reference BA of Applicant's PTO-1449). The Examiner suggests that Senter et al. teach methods of increasing activation of

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prodrugs Paclitaxel and camptothecin (CPT-11) to active drugs in human and mouse tumor cells by administration of rat serum carboxylesterase following administration of the prodrug. Danks et al. is suggested to teach that a recombinant rabbit liver carboxylesterase sensitizes human tumor cells to the prodrug CPT-11. Satoh et al. is suggested to describe the specific activity of a variety of mammalian carboxylesterases for the activation of CPT-11 to SN-38 and show that rabbit liver carboxylesterase has one of the highest specific activities for this substrate.

In Applicants' response of May 27, 2004, Applicants indicate that Danks et al. is Applicants' own publication published less than one year before the application filing date. The Examiner suggests that this is not persuasive because the Danks et al. reference is by M.K. Danks, C.L. Morton, C.A. Pawlik, and P.M. Potter, while the inventive entity of the instant application is M.K. Danks, P.M. Potter, and P.J. Houghton. It is suggested that as such, the Danks et al. reference is by another and a 1.132 declaration must be made to overcome this rejection.

Accordingly, Applicants submit herewith a 1.132 declaration indicating that while Christopher Morton and Cynthia Pawlik generated and analyzed data presented in Danks et al. (Reference AB of Applicant's PTO-1449), they did not directly contribute to the conceptualization of the present invention. Accordingly, because Danks et al. is not by another nor was it published more than twelve months prior to the present application, it is an improper prior art reference.

Further, while Senter et al. teach methods of increasing the activation of the prodrugs Paclitaxel and camptothecin (CPT-11) to active drugs in human and mouse tumor cells using a rat serum

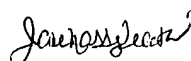
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carboxylesterase and Satoh et al. teach that the rabbit enzyme has a higher specific activity of any of the rat enzymes, these references fail to teach or suggest a rabbit carboxylesterase recombinantly produced by expressing a polynucleotide encoding SEQ ID NO:21 for drug activation. Therefore, Senter et al. and Satoh et al. do not teach or suggest all the claim limitations and therefore do not make the present invention obvious. Withdrawal of this rejection is therefore respectfully requested.

### **III. Conclusion**

The Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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